Department of Energy
Fermi Area Office
Post Office Box 2000
Batavia, Illinois 60510

SEP 2 0 2006

Dr. Pier J. Oddone, Director
Fermilab
P.O. Box 500
Batavia, IL 60510

Dear Dr. Oddone:

SUBJECT: FERMI NATIONAL ACCELERATOR LABORATORY (FERMILAB) QUALITY PROGRAM REVIEW

Reference: Letter, J. Livengood to J. Grant, dated June 23, 2006, Subject: Same As Above

Enclosed is the subject report on the Operational Awareness Program review of the Quality Assurance Implementation at Fermilab. The review was conducted during the period of July 10-14, 2006 for my office by a team of experts whose qualifications are noted in the report. The review objectives were to:

- review implementation of the Fermilab Quality Assurance Policy;
- assess the effectiveness of implementation in meeting Department of Energy (DOE) and Fermilab expectations; and
- identify any gaps and areas of improvement so that opportunities for improvement can be highlighted.

The team met the objectives within the constraints of time and the current DOE-Fermilab contract.

The review found that the Fermilab quality management program supports performance outcomes that meet the scientific and operational expectations of DOE. Fermilab states a commitment to quality excellence, implements a number of quality systems, and directs a highly competent technical staff. As a result, a number of quality elements, initiatives, and organizational practices were cited. There is laboratory-wide recognition that quality is and must continue to be a deeply ingrained feature of the Fermilab culture. This recognition is confirmed by the level of effective communication that occurs at all levels of management to produce an uncommonly clear and shared understanding of laboratory scientific and operational expectations.

Despite the current success of the program in supporting performance outcomes, there are a number of inadequacies in the structure of the Fermilab quality management program that are primarily of a documentation and assessment nature. Many of these inadequacies can be remedied through creation of governing documents that flow down from the Director's Policy and improvements to the Fermilab management assessment and independent assessment programs.

The need for a better defined quality program becomes increasingly more important for Fermilab at a time when significant organizational changes in Tevatron operations are anticipated, planning for the International Linear Collider increases, and retirement of key staff is projected. An implementation plan responding to the observations from this review would enable Fermilab to better prepare for, and successfully meet, the challenges associated with these changes in mission and staff while at the same time strengthening the overall quality of the Fermilab program.

The Fermi Site Office (FSO) would like to recognize your efforts in support of this review as well as those of Mr. James Blowers of Technical Division and Ms. Marilyn Dixon of your staff in arranging accommodations, coordinating schedules, and compiling documents. FSO also recognizes the genuine interest and strong participation of Fermilab line management during the interviews, daily status meetings, and review close-out.

Please prepare a corrective action plan and schedule for completion for those observations identified in the report as less than adequate. The corrective action plan should be submitted to this office by December 15, 2006. If you have any questions regarding this request, please contact Ms. Berline Short of my staff at extension 4197.

Sincerely,

Joanna M. Livengood

Dr. Joanna M. Livengood
Site Manager

Enclosure:
As Stated

cc: Y-K. Kim, w/encl.
B. Chrisman, w/encl.
J. Blowers, w/encl.

Fermilab Quality Program Review

DOE Fermi Site Office

July 2006

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Table of Contents

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Review Purpose and Scope

The purpose of this operational awareness review was to assess the implementation of the Fermilab Quality Assurance Policy and examine the effectiveness of the quality management program at Fermilab in meeting DOE and Fermilab expectations. The review was designed to provide observations on the implementation of the policy and the quality practices carried out on the site. These observations include comments on the level of adequacy of Fermilab quality practices as well as potential opportunities for improvement, programmatic gaps, and noteworthy practices in program implementation.

The review was designed to assess program implementation at different levels within the Fermilab organization. The team was divided into four, two-member review subteams. Two review team members focused on implementation of the Fermilab Director's Policy at the senior management level of the laboratory. Two review team members focused on the quality program implemented by two Fermilab research divisions, the Fermilab Accelerator Division and the Fermilab Particle Physics Division. Two members focused on the activities of the Fermilab Technical Division, the Fermilab organization involved in major production activities at Fermilab, while two members of the review team reviewed the quality aspects of Fermilab support activities in a number of different Fermilab organizations.

Review Approach

The review was accomplished through interviews of Fermilab management and staff, reviews of technical and operational documents and records, tours of research and support facilities, and observations of both research and support work activities. The Fermilab personnel interviewed are provided in an appendix to this report.

A generic set of criteria and lines of inquiry were developed prior to the review using Department of Energy reference documentation. The Criteria Review and Approach Documents (CRADs) and associated Lines of Inquiry for the review were used as a guide by team members in their review efforts. The review CRADs and Lines of Inquiry are included as an appendix to this report.

The two-member review subteams are listed below along with their area or review:

Senior Management
- DeVaughn Nelson, SC
- Dennie Parzyck, FSO

Technical Division
- Judy Malsbury, PPPL
- Tom McDermott, CH

Research Divisions
- John Mashburn, ORNL
- David Passarello, BNL

Support Organizations
- Berline Short, FSO
- Kate Sordelet, Ames

Qualification statements for each of the review team members are provided as an appendix to this report.

The review was conducted during the week of July 10-14, 2006. The review began with a presentation by the Laboratory Director on Fermilab quality expectations and the elements of integrated management that support quality performance. Presentations were then provided by managers from Fermilab research and support organizations on their organizational missions and the role of quality in their integrated management programs.

A daily schedule of interviews and meetings was carried out by each two member review subteam. The entire review team met each afternoon to discuss the activities of each subteam during that day as well as their observations to that point. Following the daily review team meeting, there was a debriefing for Fermilab management and all interested parties. At the end of the review, a Close-out meeting was held for the laboratory population. At the Close-out, each of the four subteam leaders summarized the observations of their subteam as well as the program gaps and the noteworthy practices that their subteam had found.

Observation Categories

The activities of the four subteams resulted in a series of observations on program adequacy, as well as opportunities for improvement, programmatic gaps and noteworthy practices. These observations are documented in this report under the following categories:

- Fermilab Policy Implementation;
- Fermilab quality program effectiveness;
- Opportunities for improvement or program gaps; and
- Noteworthy Practices.

For each observation placed in the first two categories, team members designated whether the implementation of Fermilab policy and effectiveness of quality management program implementation was "commendable," "adequate," or "less than adequate." A short description could also be provided on the benefit of each commendable observation or the negative impact of each less than adequate observation. Team members could also provide a description of the impact of a programmatic gap and or the particular benefit of a noteworthy practice.

Observations of Fermilab Policy Implementation

Observations of Commendable Implementation

Observation: The work process control activity in Technical Division Process Engineering utilizes travelers in documenting the engineering design for fabrication and assembly engineering on accelerator support jobs as well as procedures and results for measurements and testing.

The traveler system as implemented by TD provides a complete record of the project from the specifications, changes, approvals, testing and acceptance for fabrication and/or assembly.

Observations of Less than Adequate Implementation

Observation: All levels of Fermilab management consistently and unambiguously state a commitment to quality excellence and understand it to be a basic constituent of all laboratory activities. Such management statements are indicative of a quality culture but must be followed up with suitable documentation for implementing Director's Policy 10 as well as other relevant Director's policies.

The lack of documented implementation of laboratory QA policy, with the exception of the Technical Division, raises a question about implementation of the entire Fermilab system of policies. If current set of policies do not describe the current expectations, the policies should be modified to reflect those expectations.

Observation: All levels of Fermilab management refer to the use of a "graded approach" in the Fermilab quality program. This approach is not defined or described in any known Fermilab documentation so that the meaning and how it is implemented can be generally understood.

It is important that the working-level population fully understand the details of implementation of this concept in their culture. Fundamental concepts and processes of Fermilab must be defined suitably for both managers and employees. Individual interpretations may lead to confusion unless everyone has a clear understanding.

Observation: The Fermilab self-assessment program as described in the Director's Policies 10 and 20, is not functioning at the division or section level. This self-assessment element of the Fermilab quality program is specifically referenced in Director's Policy 10. While the importance of an effective self-assessment program to an overall quality program is well recognized by Fermilab management, this review shows that the self assessment program is not being implemented site wide.

A comprehensive self assessment program should be implemented to include both a Management Assessment Program and an Independent Assessment Program. The

Fermilab quality program cannot be assumed to be effective without the active participation of the organization in a systematic self-assessment program.

Observation: The laboratory director has sent correspondence on October 4, 2005 entitled *Quality Assurance - An Integrated Responsibility* to each Fermilab employee reinforcing the importance of Director's Policy 10. There is little documented evidence that the Director's Policy 10 and other related quality policies are being implemented with the exception of the Technical Division which has a documented Quality Assurance Plan.

In order to be effective, there should be follow-up instructions to ensure that management expectations are communicated and fulfilled. The policy does not provide any mechanism for the Director to determine how the policy is being implemented. This goal may be accomplished through development of quality training to communicate expected outcomes throughout the laboratory in accordance with documented requirements.

Observation: Fermilab does not have an established Document Control Program to meet the intent of Director's Policies 10 and 13. Such a program would ensure that documents were appropriately specified, prepared, reviewed, approved and maintained through a process of document control reviews, a formal document approval process, a document tracking database, and a master document file.

Obsolete documents may be inadvertently utilized by personnel, duplication of documentation may occur between Divisions/Departments or Sections, contradictions may arise between documents within organizations, documents may not be updated in accordance with established review cycles, and other external reviewers may not be able to adequately review laboratory programs.

Observation: Fermilab does not clearly identify the job specific training required for various positions consistent with Director's Policy 19 with the exception of a few specific positions such as those in the Fire Department. Fermilab training needs are identified via the Fermilab Individual Training Needs Assessment (ITNA) program primarily for environment, safety and health training and some topics required for specific positions. A significant amount of training is currently provided through mentoring or on-the-job training.

There are some work elements that require specialized and more formal training. These needs should be identified, specific training identified and implementation of that training tracked to completion as with other training in the Fermilab ITNA system.

Observation: The implementation of self assessment by the Technical Division does not satisfy the requirements of Director's Policies 10 and 20. There is no procedure that defines the basics of an acceptable peer review system. Policy states that each Division or Section Head shall insure that significant processes and activities are assessed at least once every three years. Technical Division implementation of this policy would require an average of ten assessments each year. TD-2020 includes a section describing the practice of assessing significant processes at least once every three years, but due to the

large work load, the Technical Division has established a limit of one independent assessment per year (this is also documented in policy TD-2020). .

Without appropriate guidance at the Laboratory level and procedures at the Technical Division level, the consistent effectiveness of the peer review process is unlikely and there is increased likelihood that a significant aspect of a peer review process would be missed. Such assessments are an important element of a continuous improvement program.

Observations of Fermilab Quality Program Effectiveness

Observations of Commendable Implementation

Observation: The Accelerator Systems Departments have an aggressive and comprehensive training program which facilitates operator knowledge of the accelerator complex with both written and oral examinations. The relationship between and the understanding among the various accelerator departments is an integral part of the overall effectiveness of the program.

Feedback from those interviewed from among the four Accelerator Systems Departments indicated that ongoing close communication and cooperation with control room personnel has been an integral part of the successful operational performance of the accelerator complex. The motivation and pride of the departments' staff was very obvious.

Observation: The Accelerator Division Call-In and Fix-List web-based processes provide real-time information on accelerator-related issues. These reports are reviewed and acted upon in a timely fashion by the responsible individuals. Call-In and Fix-List data are reviewed by the Department Heads as well as the Deputy Accelerator Division Head.

Observation: For the purpose of Personnel Training and Qualifications, new staff members follow an Operations Department team for several months and are located in the control room during their shifts to learn first hand the details of machine operation.

Observation: The Accelerator Systems Departments are closely linked to the Accelerator Operations (AO) Department for operational improvements through an assigned machine specialist from AO. Each specialist attends the respective Accelerator Systems Department meetings, participates in the preparation and modification of operating procedures and participates in scheduled organizational meetings. Meeting summaries are documented in Fermilab web sites.

Observation: The Accelerator Division Controls Department maintains configuration of control software code through use of the Code Management Program to address developers' access to the code, the testing of revised code, work in progress, and the release of revised code.

In the successful change over from the old VMS and PDP-11 code to the new Linux code, a liaison from each Accelerator Systems Department was assigned to the project. The project liaison team effectively reviewed the old code, tested the new code, and classified the code based upon its impact on the operation of the accelerator. The classification not only successfully defined the impact of the code but also dictated the appropriate level of approval required prior to release.

Observation: The Accelerator Division Controls Department purchases both populated and unpopulated printed wiring boards. The purchased boards are purposely not cutting-

edge technology because the Accelerator Division Controls Department engineers favor simple designs and mature technology for enhanced reliability.

Observation: The Particle Physics Division (PPD) has an extensive, formal peer review process for papers prior to publication. Data quality is continually reviewed, where the purpose is to look for minor problems before they become major problems as more than a million channels of data are processed to get the record of the vital few events needed by the experimenters. The self-assessment program for the research divisions includes assessment of experiment availability and efficiency and the number of research papers published.

Observation: The configuration of code installed by the Accelerator Division Interlocks Group is maintained so that code cannot be downloaded to Programmable Logic Controllers (PLCs). The affected interlock system must be taken down to revise code as the PLCs are purposely not networked. New code is reviewed and approved by the Accelerator Division Interlocks Group and the Fermilab ESH Section. Requests for changes to the code are made by the Radiation Safety Officer and documented.

Observation: The PPD Mechanical Department uses industry standards such as ASME Y14.5M in their drafting process. A request form is used which can either request the preparation of a new drawing or describe "significant" changes to a released drawing with "significant" described as requiring more than 4 hours of designer time.

Observation: The PPD Division Mechanical Department CAD server is located outside of their building complex. This assures that there is a back up if the original or "master" paper drawings are ever destroyed in a fire or storm affecting the PPD building complex.

Observation: The PPD Technical Centers use formal documentation for the fabrication of detector products and assemblies. Work plans control all projects, and include a hazard analysis if needed. Travelers (historical records that travel with a part or assemblies) are used to document the status of parts and assemblies during fabrication. Travelers are reviewed by Technical Center supervision and their customer. Workstation logs keep details pertinent to the use and performance of a production or measuring machine.

Observation: The PPD Technical Centers maintain a database of skills and capabilities of all personnel. The Technical Centers cross-train their personnel to enhance their overall capability and responsiveness.

Observation: The PPD Technical Centers maintain a calibration program and also a metrology center. The calibration program covers both procured commercial equipment and specialty equipment built in-house. Calibration and maintenance programs follow manufacturers and local recommendations.

Observation: The Fermilab Human Resources Compensation Department has a formalized Position Description System. The position is prepared and reviewed by Compensation, coded in PeopleSoft, added to the human resources appendix of the

contract, and posted to the web with a link to the associated pay range. The formality of the Position Description System clearly helps define the roles and responsibilities of employees throughout the organization.

Observation: The Fermilab Performance Evaluation Process includes a notification process, performance evaluation form, associated Performance Evaluation Training module along with a method for ensuring individuals receive their evaluation on an annual basis. All elements of the Performance Evaluation System are being addressed, including a revamp on the Performance Evaluation Training Module.

The process could be expanded to capture the primary work activities and associated percentage of time in order to further clarify the roles and responsibilities of individual's at the Laboratory. The Annual Performance Review Notification Letter could include a review of the individual's ITNA and Training Profile.

Observation: The Fermilab Training and Development Department has prepared a series of training modules for their new supervisors/managers, which include training on Management within the Law, Behavioral Interviewing, and Interaction Management.

The Fermilab Management Practice Seminars, in particular, provide supervisors and managers with a foundation of managerial skills to perform their duties effectively.

Observation: The Fermilab Procurement Department has developed an Issues Database which is integrated into their main Oracle database system. This system effectively tracks customer issues and logs all communication and corrective actions on an issue until it is closed. Summary Reports can be generated from the Issues Database for tracking and trending purposes.

The Fermilab Procurement Department is extremely customer focused by ensuring customer issues are resolved promptly and by ensuring their work processes are efficient.

Observation: Fermilab Human Resources solicits customer feedback on several of their work processes and recently prepared an electronic survey on Customer Satisfaction with Visa Office Services. Procurement also routinely initiates customer service evaluations.

The Human Resource Office and Procurement Department are customer focused and actively request feedback so that they can modify their work processes to meet customer requirements.

Observation: The Technical Division Testing and Instrumentation organization produces formal documents on data acquisition and controls specifications for testing and measurements equipment. The organization also provides a cost and schedule estimate for project proposals that is well documented and includes brief risk assessments.

This process provides an accurate cost for the projects as well as feedback in costing and scheduling testing products. The process provides a complete document on design and operating parameters for the designer and user.

Observations of Adequate Implementation Observation:

Observation: The Accelerator Division "electronic logs" contain the record of accelerator tuning adjustments for fixes or improvements. Formal presentations to lab-level meetings are made that report changes made and problems solved. The individual motivation and pride associated with this process is evident.

Observation: The Accelerator Systems Departments employ a graded approach to determine if formal reviews of proposed work and associated hazards are required. A Department Head makes the decision based on cost impact, impact on operations, and the degree of coordination with other departments.

Observation: The Accelerator Systems Departments employ a graded approach process for machine performance improvements. A Department Head makes each decision based on review of the proposal by department personnel, presentation at an all departments meeting, and the performance of a Run Coordinator scheduled study that includes completion of the study and presentation of the study results.

Observation: The Accelerator Systems Departments utilize a formal change analysis and other quality techniques to recover from unexpected failures or changes that challenge their current knowledge and skill.

Observation: The Accelerator Division Controls Department sends employees to outside technical training provided by Cisco and Microsoft.

Observation: The Accelerator Division Controls Department provides programmers to support the various Accelerator Systems Departments in a matrix relationship when code is to be developed.

Observation: PLC's are selected based on engineers' preference, and vendors are selected by the Procurement Department unless specified by the engineer.

Observation: The Accelerator Division Interlocks Group maintains procedures that describe the testing of the various functions of the interlock system. Drawings and schematics that define the interlock system are prepared and maintained by the group and are approved by them. Testing requirements for the interlock system are well documented.

PLC code used in the access control system performs only administration functions. The PLC code does not perform/control any critical safety functions. The Department Head

conducts walk-downs and quarterly assessments of interlock systems including laser, radiological, and confined spaces

Observation: The use of electronic logs and other departmental processes in the Particle Physics Division support the goal of improved scientific understanding and the training of new scientists. Departmental meetings are held to discuss operational issues. Physicists work closely with engineers and technicians to maintain and upgrade detectors.

Training in the Particle Physics D0 and CDF Departments is based upon the technical area of responsibility within the specific department. Training status is maintained in the Fermilab training database. Mechanical and electrical technicians are drawn from the Particle Physics Division Mechanical and Electrical Departments. Control rooms are staffed with collaborators, not just department personnel. Fermilab insures collaborators are trained .

Observation: The Mechanical Department (PPD) drafting process is an orderly professional approach to drafting, checking, and approving products. Training is simplified by use of hard copy for the official record, not 3D computer models or other techniques now becoming available. A reference manual is maintained that contains divisional drafting standards and applicable ANSI standards. The supporting I-DEAS manual is available on line.

Drawings without approvals are not considered released. The revision history block is used, i.e. description of change, checked-by and date. All changes to drawings are indicated on the drawing in the revision field using industry standard protocols, as opposed to separate engineering change notices.

Observation: PPD Technical Centers use specialized and calibrated equipment to fabricate products/assemblies for experimental applications. The project or facility customer is responsible for all technical requirements, down to the details of design and process specification, and monitors construction or fabrication.

When Technical Centers make parts for the PPD Mechanical Department or Electrical Engineering Department, the latter provide the specifications, and procure/provide all required material.

Observation: Facilities and Engineering Services Section has an extensive set of documents to direct all of their work activities including the Engineering Group Handbook, Construction Document Review & Distribution Procedure, AE Handbook, CAD Standards, and Engineering Standards Manual in addition to using all applicable regulatory codes. The Division utilizes sound records management strategies to maintain both hard-copy and electronic drawings.

Items and processes appear to be designed using sound engineering/scientific principles and appropriate standards.

Observation: Particle Physics Division has an Operational Readiness Review System for experiments that includes a screening process, Preliminary Safety Assessment Document (PSAD), defined requirements for preparation of a SAD, and an approval sequence before an experiment can become operational. The Procedures for Experimenters Manual is well done and provides Fermilab expectations for experimenters. An Employee Recommendation Program has been implemented as well as an ES&H Open House where safety topics are discussed.

Observation: Fermilab ES&H Section has several systems that meet quality assurance principles including, Institutional Training, Operational Readiness Reviews, Calibration Programs, the Senior Safety Officer Program, and Lessons Learned Program.

The information provided during interviews with ESH Section staff and the corresponding documentation on the Fermilab ESH web page meets quality assurance expectations.

Observation: The Technical Division Testing and Instrumentation Department has identified department objectives for improving tools used in managing work. Three areas for improvement include data management that is being transitioned to web-based data management, content management schemes, and configuration management.

Observations of Less than Adequate Implementation

Observation: Some Accelerator Division Control Room procedures were out of date. Uncontrolled manuals and procedures were present in the Control Room. Turn-on forms are used in the Control Room and appropriate approvals are obtained. While turn-on forms had revision numbers and dates, the forms were not linked to any procedure which described when or how the form should be used.

Observation: The Accelerator Division Control Room operators are not required to document that they have read the "Hot Items List" maintained in the Control Room. A system is not in place to review and approve operator aids.

Observation: The Accelerator Control Room has a "Department Procedures" manual for procedures prepared by the Accelerator System Departments. The purpose of these procedures is to provide the operators with instructions when a functional system has been modified and requires additional/revised instructions. Procedures were found within a manual stamped "Uncontrolled Copy". It was stated that controlled copies are not maintained in the Control Room

Uncontrolled documents, which may conflict with current operator training, may create a situation where an individual unknowingly performs a task improperly or in an unsafe manner.

Observation: Operational procedures, prepared with the aid of Accelerator System Departments, are reviewed by the Operations Department Head. After review, a decision

is made as to whether the procedure will be maintained in the Control Room. It was unclear whether this decision information is transmitted back to the affected Accelerator Systems Departments.

Observation: Some Accelerator Control Room training material (e.g. flow charts, lesson material and tests) was dated 1997 although completed training material presented shown to reviewers had been revised since that time. It was explained that the training material is reviewed and updated as necessary on an annual basis.

Outdated documents that may conflict with current operator training may create a situation where an individual unknowingly performs a task improperly or in an unsafe manner.

Observation: Personnel Sweep Maps used by the operators and prepared by the Accelerator Division ESH Department were not controlled. The maps, some of which had instructions typed on them, did not contain information on what group prepared the document, the individual who approved them, or the revision number or date of issuance.

Use of uncontrolled maps could impact worker safety. Only those maps that contain appropriate identification, revision control, and approval control should be in the Main Control Room.

Observation: The Accelerator Systems Departments do not have written procedures, even though procedure BDAP-01-0001, Beams Division Procedure Requirements, would seem to require these procedures. Despite the lack of procedures, the four Accelerator Systems Departments interviewed within the Accelerator Division are consistently consistent in how they perform work within their own organization and in how cross functional work and communication is performed.

Observation: The Accelerator Systems Departments do not require members to sign approval of design specifications, even when they are produced by engineering departments for requirements provided by the Accelerator Systems Departments.

Proper engineering discipline requires that the basis for design is known and that design outputs are checked against input requirements. Formal approval of the specifications would reduce the possibility of a miscommunication of performance requirements between the departments.

Observation: No formal configuration process existed within the Accelerator Systems Departments. The departments rely on the configuration processes in the Mechanical, Electrical and Cryogenic support organizations. This would be a concern if the Accelerator Systems Departments prepare their own drawings or specifications.

Observation: There is no documentation of the calibration status of measuring and test equipment within those Accelerator Division Departments reviewed. While it is understood that the measuring and test equipment reviewed is not used for critical

applications, it would be an issue if the equipment were used for product or material acceptance.

Observation: While there are procedures which define the various practices within the Accelerator Division Interlocks Group, the dates of the procedures range from 1992 to 2006. This does not comply with a triennial review requirement in the Beams Division Administrative Procedure BDAP-01-0001, Beams Division Procedure Requirements, which also prescribes a documentation of each review.

Observation: The Quality Control Group of the Technical Division Material Control Department is responsible for receiving inspection documentation. The procedure that defines the processes used by this group to perform this function has not been updated since 1991 and does not reflect recent changes made to the processes.

Observation: The Technical Division Machine Shop procedures were dated from 1992 to1993 and have not been updated. Machine Shop personnel are provided a manual labeled the "TD Machine Shop Safety Manual." Review of the manual determined that the Lockout/Tagout procedure for machine tools was missing an approval date and a procedure for machining radioactive material was no longer valid. The supervisor stated that staff are made aware of new procedures when discussed in "tool box" meetings.

Observation: Technical Division Quality Control, under Process Engineering, is performing some specialized testing without current procedures including a procedure for "hi-pot testing.". While a procedure for "hi-pot testing" of a specific coil was found, nothing applicable to a general testing process was found.

Observation: Fermilab lacks a site-wide cohesive Job Specific Training (JST) Program. A quality JST Program will help ensure personnel have the appropriate training to perform their assigned work activities safely and efficiently.

Opportunities for Improvement or Program Gaps

Opportunity for Improvement: The review team did not have the opportunity to provide a comprehensive review of the Fermilab suspect/counterfeit items program. Training on detecting suspect/counterfeit items was provided by ANL. It was noted that DOE also provides an excellent course on Suspect/Counterfeit Items free to both DOE employees and laboratory personnel. The DOE course could increase the awareness of Fermilab employees on the issue of suspect/counterfeit items and their capability to identify such items.

Program Gap: Fermilab Records Management System does not meet DOE established life-cycle records management requirements for all record formats. The decentralized system relies on File Coordinators and Clerks to establish records series, assign retention schedules, prepare file plans and index inactive files for storage. The Records management System is not cohesive due to the lack of a centralized records management database. A Fermilab Disposition Procedure should be developed to ensure a legal/defensible disposition process. Records management personnel also should receive database training to support an integrated records management system.

The Fermilab Vital Records Protection Plan needs to be updated to meet new vital records requirements. This includes a Vital Records Management Plan that directs a process for identifying, protecting, controlling access, and ensuring availability of records that specify how the organization will operate both during and after an emergency or disaster.

Program Gap: Fermilab does not have an established Procurement Quality Assurance Rating System although Fermilab Procurement has implemented a number of workflow rules in the Oracle Procurement Module that helps ensure that sensitive items are reviewed and approved by the proper authorities prior to purchase. Fermilab would benefit from an automated quality assurance rating system that delineates certain procurements receive an initial review and/or a receipt review by in-house expert.

Program Gap: The standard used for the calibration of mechanical measuring and test equipment by the Technical Division Material Control Department is not recorded on the certificate of calibration. Fermilab Director's Policies do not provide requirements for calibration. The Technical Division Quality Assurance Program does contain requirements for calibration but does not require that the standard used for calibration be recorded.

Program Gap: Fermilab does not have a governing Quality Assurance Manual that meets the minimum quality criteria as documented in several current quality assurance standards. Although the DOE QA order is not included in the Fermilab necessary and sufficient standard set, a QA manual is considered to be a typical component of a formal institutional quality program.

Noteworthy Practices

Noteworthy Practice: An interview with senior laboratory project management has highlighted Fermilab efforts to apply quality assurance criteria and principles to specific operational activities at Fermilab. To date, the implementation of these criteria and principles to project management are recognized as having contributed to the success of the Fermilab Run II Upgrades and the Fermilab Proton Plan. These successful applications have demonstrated the strength of such quality management approaches for operational activities.

Noteworthy Practice: For large projects involving magnet production, a formal close out report is generated with three sections that include a production summary describing the work performed and the deviation requests generated, the project cost/schedule summary, and the project lessons learned. The lessons learned are systematically incorporated into future work activities under a continuous improvement process to help assure that the corresponding problems do not recur.

Noteworthy Practice: Fermilab has a well integrated Institutional Training Program covering both professional development and ES&H training modules based upon a sound needs assessment program component (e.g. ITNA), a comprehensive electronic record keeping system (i.e. TRAIN database), detailed Employee Training Summary Reports, and an automated notification system. The Institutional Training System is impressive. All participants demonstrate a thorough understanding and appreciation of the system. Further development of the system is encouraged to integrate other training requirements.

Noteworthy Practice: Fermilab Scientific and Technical Information (STI) Program is fulfilling the requirements of DOE O 241.1A, Scientific and Technical Information in a quality manner. Scientific and technical information items are subjected to patent review, technical reviews, internal electronic submission process review, transfer of copyright preparation, sensitivity reviews, electronic submission to the Office of Scientific and Technical Information, and archiving. The program ensures that scientific and technical information is identified, processed, disseminated, and preserved in a manner that enables the scientific community to locate and use information resulting from research activities. The program has also completed the OSTI Harvesting and Legacy Initiatives.

Noteworthy Practice: A Fermilab *Human Resource Answer Book* has been developed that describes all of the major human resources workflow processes with associated links to supporting forms and guidance. The New Employee Training module is being revamped with a supporting New Employee Orientation Web Page. The Performance Evaluation Training Module is being enhanced to incorporate the *SMART System* for conducting effective performance evaluations. The Job Description Posting is being revamped. These items all demonstrate a process of continuous improvement for excellence.

Noteworthy Practice: The control of design drawings by Technical Division Design, Drafting and Computing Information Systems includes electronic versions of all design

data maintained in the X-DCS database, including Bills of Materials and CAD drawings from originals through fabrication. All engineering changes are controlled through the use of engineering change orders. Engineering release and engineering change orders require the formal approval of the project engineer. In addition, the lab-wide implementation of Teamcenter Engineering will standardize the Fermilab approach for comprehensive control of mechanical drawings.

Discussion of Observations

The Fermi Site Office QA Review found that the Fermilab quality management program supports performance outcomes that meet the scientific and operational expectations of DOE. Fermilab has instituted a number of quality systems, states a commitment to quality excellence, and directs a highly competent technical staff. However, Fermilab needs to establish an integrated Quality Assurance Program that meets the minimum quality criteria as recognized in several current quality assurance standards. This action will be achieved by formally documenting many of Fermilab's current excellent processes and quality practices, as well as, documenting additional quality systems to meet the expectations as outlined in Fermilab's Directors Policy on Quality Assurance.

Fermilab has established a number of quality systems that are foundational for its Quality Assurance Program. The Institutional Training Program is impressive as it ensures that employees training needs are properly identified and tracked. Training information is effectively shared with employees and their supervisors, while the automated notification system helps ensure training compliance.

Another notable core quality element is Fermilab's Scientific and Technical Information (STI) Program. The STI Program ensures that information is identified, processed, disseminated, and preserved in a manner that enables the scientific community to locate and use information resulting from research activities. It was evident that the program meets all the established requirements of DOE O 241.1A, Scientific and Technical Information, and has successfully completed several large Department of Energy initiatives prior to their targeted deadlines.

The Laboratory Services Section displayed a number of quality initiatives throughout their organization. A Fermilab *Human Resource Answer Book* was developed that describes all of the major human resources workflow processes with associated links to supporting forms and guidance. Clear roles and responsibilities have been conveyed to Laboratory personnel as imparted by a formalized Position Description Process and a sound Performance Evaluation System.

Customer service satisfaction and continuous improvement is also a part of Fermilab's excellent organizational practices. It was observed in several departments that customer feedback was solicited via electronic surveys. These surveys not only targeted customer satisfaction but sought information regarding changes to current work processes. In addition, organizations actively look at ways to make their processes better. Many organizations within Technical Division continuously strive to improve the processes, documentation and tools they use in the design, testing, and production of magnets.

Fermilab does not have governing documents flow down from the Director's Policy to provide appropriate guidance to line organizations on performance expectations for quality control and assurance. This documentation is especially needed to establish criteria and guidance in the areas of records management, procurement, and management and self-assessments. As part of the overall quality management program, Fermilab needs

to develop a comprehensive self-assessment program, including a Worker Observation Program and Independent Assessment Program.

Fermilab's Records Management System does not meet the expectation of life-cycle records management for all record formats. A requirements analysis for an Electronic Records Management System (ERMS) and the implementation of a centralized database is essential for maintaining records in accordance with DOE and established legal requirements. Furthermore, procedures must be prepared and implemented to effectively deal with retention, disposition and vital records issues.

There is laboratory-wide recognition that quality is an absolutely necessary element of all work activities and everyone's goal. This recognition is a deeply ingrained feature of the Fermilab culture. This was confirmed through interviews and by observing several daily and weekly meetings where key personnel at all levels of management gather to discuss operational status, current work activities, and priorities for future work. The level of communication observed is one of the important strengths of the Fermilab quality management program. As a result, from senior management to the working level staff members, there is an uncommonly clear and shared understanding of laboratory scientific and operational expectations.

The need for a better-defined quality program becomes increasingly more important for an organization undergoing significant internal change. The impending end of Tevatron operations, planning for the International Linear Collider, and the increasing number of staff reaching retirement age establishes Fermilab as an organization facing such change. An implementation plan responding to the observations from this review will enable Fermilab to better prepare for, and successfully meet, the challenges associated with these changes in mission and staff while at the same time strengthening the overall quality of the Fermilab programs.

Appendix A

Fermi Site Office QA Review Schedule Memo to Fermilab

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Department of Energy

JUN 23 2006

Mr. John R. Grant,
Assistant Director
Fermilab
P.O. Box 500
Batavia, IL 60510

Dear Mr. Grant:

SUBJECT: ASSESSMENT OF QUALITY ASSURANCE IMPLEMENTATION AT FERMILAB JULY 10-14, 2006

The Fermi Site Office (FSO) has scheduled an Operational Awareness Program review of Quality Assurance implementation at Fermilab. Dr. DeVaughn Nelson from the DOE Office of Science will lead the review team comprised of the following individuals:

Judy Malsbury, PPPL	Dave Passarello, BNL
Tom McDermott, CH	Berline Short, FSO
John Mashburn, ORNL	Kate Serdelet, Ames
Dennis Parzyck, FSO	

The objectives of this review are to:

- Review implementation of the Fermilab Quality Assurance Policy
- Assess the effectiveness of the implementation in meeting DOE and Fermilab expectations
- Identify any gaps and areas of improvement so that opportunities for improvement can be highlighted

Please provide a presentation to the team on July 10 on the following points:

- Fermilab organizational structure, program responsibilities, levels of authority, and organizational interfaces
- Quality assurance processes to support the work being performed
- Quality assurance oversight program
- Mechanisms to promote Integrated Safety Management and Quality Assurance

Dr. Nelson may contact you to obtain reference information on your program. Some members of the team are already involved in review of reference information on your area. Dr. Nelson has requested that Fermilab representatives be available to support the team members. Daily briefings will be provided during the review and a close-out meeting will be held on Friday afternoon, July 14.

If you have questions, please contact Jon Cooper at 840-4285.

Sincerely,

Original Signed by
Dr. Joanna M. Livengood
Site Manager

Dr. Joanna M. Livengood
Site Manager

cc: P. Oddone
K. Stanfield
B. Chrisman
D. Nelson, SC-31.1

Appendix B

Documents Reviewed

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Documents Reviewed

http://tdserver1.fnal.gov/hq/SA/FY06/DOE_QA_Audit/Documents.xls
Fermilab ES&H Manual (FESHM) 1030 Environment, Safety and Health Responsibilities, June 2005
FESHM 1040 Assurance Program June 2006
FESHM 1040.1 ES&H Self Assessment Program May 2006
FESHM 1040.2 ESHTRK Procedures June 2006
FESHM 4010 ES&H Training Program, July 1998
Directors Policy Manual June 12, 2000
Fermilab Procurement Policy and Procedures Manual, December 22, 2003
Fermilab Engineering Standards
Fermilab Integrated ES&H Management Plan November 2003
Department and division web pages
Beams Division Administrative Procedure BDAP-01-0001, Beams Division Procedure Requirements
Personnel Sweep Maps
Training material binder
Operational procedures, "Department Procedures" manual
Procedures for testing functions of the interlock system
Design and Drafting Request form
Silicon detector travelers and microbonding station log
Memo, J. Frazier to D/S Heads and Administrators, dated June 20, 2006, Subject: Annual Performance Review
Performance Review Form http://lss.fnal.gov/elr/perform_rev.html
Professional Training Curriculum web page http://lss.fnal.gov/train-dev/index.html
Leadership/Management Curriculum webpage http://lss.fnal.gov/train-dev/leadcurric.html
ITNA questions webpage http://www-esh.fnal.gov:8001/Train_DB/
FY05 Self Assessments: Human Resources – Employment, Equal Opportunity and Counseling, and Professional and Organization Development
Oracle Electronic Business Suite (eBS) – Production System Operations Action Tracking Item NOs: 3863, 5505, 5510, 5511, and 5595
Incorporated in the URA contract Records and Technical Publications
Generic letter, K. Duerr to Fermilab authors, Subject: CONF number and to upload copy of paper
Generic letter, K. Duerr to Fermilab authors, Subject: Conference Office Proposal
Generic letter, K. Duerr to Fermilab authors, Subject: Work for Hire Classification
Total number of published papers by year since 1990
Technical Publication ORTA Review (pink slip)
Technical Publication Review (blue list of reviewers)
eHarvesting using SPIRES H. O'Connell presentation, April 2005
Scientific and Technical Document Submission System Presentation
Records Storage and Disposition (RSD)
E. Phillips' Response to Quality Assurance Review of Fermilab Reference Criteria and Lines of Inquiry, dated July 2005
Fermilab Vital Records Protection Program Rev. 12/93
Letter, J. Priest to file, Fermilab offsite Record Storage compliance assessment of the Federal Companies Glendale Heights, Illinois Facility
List of Records Management Coordinators
http://www.fnal.gov/faw/RecordsManagement/coordinators.html
Individual Training Summary for J. Kofron
ITNA Question Map
A/E Handbook – September 1999, §11, Quality Control
Real Property Asset Management presentation at the Facilities Manager's Meeting, November 2003
K. Schuh's Particle Physics Division ES&H/BMS Department descriptions in preparation for FSO QA OAP assessment, dated July 2006
NuMI Project ES&H/QA Review Process, Dated October 2003

Letter J. Strait to B. Griffing, dated September 7, 2005, Results of FY 2005 PPD ES&H Plan
Letter G. Brock to P. Oddone, dated November 18, 2005, FY 2006 PPD ES&H Plan FY 2005 Results
http://www-esh.fnal.gov:8001/ESH_Plans/FY2006/PD.pdf
PPD Operating Manual
http://tdserver1.fnal.gov/hq/SA/FY06/DOE_QA_Audit/Web_docs/PPDMANUALTOC.pdf
TD Overview presentation July 10, 2006
TD Organization Chart July 2006
Training Completed Report TD606001/CR TD Machine Shop Surveyor 4/14/90 – 07/13/06 (Policy TD 6060 training)
Training Completed Report FN000005/CR Crane Operators 01/01/02 – 07/13/06
Project flowchart
TD Business Processes 28 Feb 2003
Job Description - Process Engineering 22 Feb 2002
TD Policy Matrix
TD Policies and Procedures Manual, TD 2010, 2020, 2030, 2040, 2050, 2060
TLL 400MeV DC Lambertson Magnets 10 June 2003 (Example of project closeout report)
Booster Pulsed Septum (BSE) 23 Feb 2005
IDHX Trim Dipole Magnets 10 May 2004
Traveler System 5520 Es 333807 28 Mar 2006
LHC Outer Coil Winding Traveler December 17, 2003
Fermi MI Wide Aperature Quad Quarter Core Stacking August 17, 2005
Certificate of Calibration Micrometer Depth 6/30/06
TD Parts Routing Form Aluminum Clamp July 10, 2006
Quality Control Report Form for Discrepancies L1 RE Pole w/ Radius 6/16/2006
Material Control Ordering Formula
IB2 Flow of Devices and Data 12 April 2001 (TD 2030 Device Data Management System)
Procedure for flow of requisitions between TD and other Divisions (Projects) dated May 27, 1997
Procedure for flow of parts for initialization, processing, and distribution of ER & ECO
TD Engineering Release (ER) form Blank Revised May 19, 2003
TD Engineering Change (ECO) Order May 19, 2003
Engineering Release and Engineering Change Order Processing Specifications 5520-ES-360000
Booster Corrector Coil Measurement System Cost and Schedule Estimate, 2/14/2006
Booster Corrector Test Stand System Checkout, Rev 0, June 13, 2006
Booster ORBMP Magnet Test IB-2 ORC February 28, 2006 compilation
DAQ Projects Document Index
LHC Test Stand (Stand 4) Data Acquisition (DAQ) and Controls Requirements Specification DAQ 99 030, January 13, 1999
Teslatron II Power System ICB Engineering Lab ORC 4/10/2006
Appendix B Modification No. M344. D. Self Assessments
Fermilab FY2005 Self assessment Process Assessment Report for Technical Division, 03 Aug 05
Machine Shop Welding Program
TD 2005 01 TD Welding Program – Audit Checklist, 02 Aug 05
Fermilab FY2005 Self assessment Process Assessment Report for Technical Division, 17 Feb 06
2006 01 TD Calibration Program – Audit Checklist for IB4, 02 Aug 05
2006 01 TD Calibration Program – Audit Checklist for VMS, 02 Aug 05 (TD 2010 2/01 p 36 of 39)
2006 01 TD Calibration Program – Audit Checklist for IB1, 02 Aug 05
2006 01 TD Calibration Program – Audit Checklist for IB2, 02 Aug 05
T & I Calibration Requirements Standard PROC-03-001, Rev No. 1, 2/16/06
TD QC Department Calibration Due Listing by Storage Location 2/20/06
TD Head Self Assessment of the Test & Instrumentation Department, 1st Quarter CY2006, March 2, 2006
Self Assessment Form for the TD Magnet Design, Construction & Testing, October 2005- March 2006
Self Assessment Form for the Process Engineering, Accelerator Component Production QA Management & Documentation, 28 Mar 2003

Welding Procedure Specification WPS No ES155000 4-14-81 compilation of docs
Physical Test Report of Welding Procedure Qualification Tests PQR 810414 4-21-81

Welder Qualification Test Record 4/13/1981

Letter, J Livengood to D. Erbschloe, dated March 2006, Subject: Assessment of the Fermilab Welding Program

Letter, G. Kobliska to V. Yarba, dated April 14, 2006, Subject: 2006 2nd Quarter Report for the Material Control Department

Letter, M. Lamm to V. Yarba, dated April 14, 2006, Subject: 2006 1st Quarter Report for the Material Control Department

2006 2nd Quarter ES&H Quarterly Report for the Test and Instrumentation Department dated 04/14/2006, C. Sylvester

Letter, G. Kobliska to V. Yarba, dated April 14, 2006, Subject: 2006 1st Quarter ES&H Self Assessment Report for the Material Control Department

Letter, M. Lamm to V. Yarba, dated April 13, 2006, Subject: 2006 1st Quarter ES&H Self Assessments Report for the Magnet System Department

Letter, R. Hiller to R. Sood, dated April 13, 2006, Subject: 2006 1st Quarter ES&H Self Assessment Report for the Machine Shop

Letter, M. Lamm to V. Yarba, dated January 17, 2006, Subject: 2005 4th Quarter ES&H Self Assessment Report for the Magnet Systems Department

Letter, G. Kobliska to V. Yarba, dated January 13, 2006, Subject: 2005 4th Quarter ES&H Self Assessment Report for the Material Control Department

Letter, L. Ramirez to R. Sood, dated January 11, 2006, Subject: 2005 4th Quarter ES&H Self Assessment Report for the Machine Shop

Letter, B. Andree to V. Yarba, dated January 23, 2006, Subject: 2005 4th Quarter ES&H Self Assessment Report for Design Drafting/Computer Information Systems

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Appendix C

Personnel Interviewed

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Interviews

P. Oddone, Fermilab Director
R. Grant, Assistant Director
S. Holmes, Associate Director
R. Dixon, Accelerator Division Head
B. Chrisman, Chief Operating Officer
P. Czarapata, Engineering Head
J. Strait, Particle Physic Division Head (for H. Montgomery, Associate Director)
E. Temple, Head of the Office of Project Management
D. Hoffer, Office of Project Management
R. Mau, Accelerator Division Accelerator Operations Department Head
K. Gollwitzer, Accelerator Division Antiproton Source Department Head
I. Kourbanis, Accelerator Division Main Injector Department Head
R. Moore, Accelerator Division Tevatron Department Head
E. Prebys, Accelerator Division Proton Source Department Head
J. Patrick, Accelerator ESH Department Head and Interlocks Group Leader
J. Anderson, Accelerator ESH Department Head and Interlocks Group Leader
M. Lindgren, Particle Physics Division CDF Department Head
L. Stutte, Particle Physics Division D-Zero Department Head
J. Rauch, Particle Physics Division Mechanical Department, Design and Drafting Deputy Group Leader
K. Kephart, Particle Physics Division, Technical Centers Associate Head
T. Hawke, Particle Physics Division Technical Centers Microbonding Leader
K. Van Vreede, Laboratory Services Section (LSS) Head
B. Brooks, LSS Deputy, Training & Development Manager
B. Jurkiw, LSS Compensation & VISA Manager
J. Frazier, LSS Employment & Employee Relations,
D. Carlson, Business Services Section (BSS) Head
J. Irvin, BSS Assistant Head
J. Collins, BSS Procurement Manager and J. Hall
H. O'Connell, BSS Information Resources Department Manager
K. Duerr, BSS STI Manager
M. Dixon & E. Phillips, Former Record Managers
E. Clark, Accelerator Division Record Coordinator
R. Ortgiesen, Facilities Engineering Services Section (FESS) Site Services Manager
E. Crumpley, FESS Engineering Manager
J. Kofron, ES&H Section Trainer,
M. Logue & D. Cossairt, ES&H Section Associate Head(s)
J. Blowers, Technical Division, Quality Assurance Officer and Process Engineering Group Leader
M. Lamm, Technical Division, Magnet Systems Department Head
D. Harding, Technical Division, Magnet Systems Department Associate Head
T. Beale, Technical Division, Material Control Department, Quality Control Group Leader
J. Brandt, Technical Division, Design & Drafting and Computing & Information Systems Department, DD Group Leader
C. Matthews, Technical Division, Machine Shop Department Head
C. Sylvester, Technical Division, Test & Instrumentation Department Associate Head
J. Zweihbohmer, Technical Division, Material Control Department Associate Head and Acquisition Group Leader
B. Jensen, Technical Division, Magnet Systems Department, Traveler Coordinator
D. Gaw, Technical Division, Magnet Systems Department, Inspecto

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Appendix D

FSO Quality Assurance Review CRADs/Lines of Inquiry

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FSO Quality Assurance Review CRADs/Lines of Inquiry

Program/ Program Implementation

Contractor management has an integrated quality management program which is implemented per the Fermilab Director's Policy Manual and which is consistent with generally-accepted quality principles and criteria as those expressed in 10 CFR 830 and DOE O 414.1C.

Contractor utilizes appropriate standards consistent with contractual or regulatory requirements and specific work activities

Contractor has integrated quality management requirements with other management requirements (i.e. ISM).

Quality documentation is "tailored" commensurate with the nature of the work, skills required to perform the work, hazards, and contractual and regulatory requirements.

Contractor's program emphasizes senior management commitment to quality and safety for all work and every employee in the organization.

Contractor has identified a management position responsible for the Quality Assurance Program.

Requirements have been established so that personnel involved in quality assurance activities have appropriate experience, knowledge, and skills.

Contractor quality assurance program performance data are reviewed by contractor management as part of performance evaluation.

Management ensures that persons hired or transferred into new positions meet the appropriate requirements.

Contractor quality assurance program includes methods for the flow down of quality requirements to subcontractors and suppliers.

Lines of Inquiry:

- Has a quality assurance program document been developed and approved by contractor management?
- Does the program document describe the management processes for the management of work?
- Has the laboratory considered using appropriate national/international quality standards?

- Are contractor work controls consistent with accepted standards?
- How does the laboratory assure that managers plan for an up-front quality system to support the work to be performed?
- What information about the up-front system is provided to all employees?
- What support services are available to help managers pursue quality?
- How does management ensure that the priority of quality is not compromised by cost and schedule considerations?
- How are important work processes determined by an organization as to whether they are documented and require staff training?
- Does contractor management communicate an expectation of worker accountability for quality?
- How does laboratory identify the appropriate administrative and hazard controls before work is performed?
- Is there a contractor policy to use a "tailored" approach for the development of procedures?
- What process or system ensures the use of approved instructions or procedures for specified work activities?
- Describe the organizational structure responsible for quality oversight.

Management and Independent Assessments

Management assessments and independent assessments are planned, scheduled, conducted, and results are documented.

Quality problems are identified, corrected, and personnel are trained on the resulting changes.

Managers view their participation in the quality assessment process as essential.

Management ensures there is sufficient authority and freedom for independent assessment teams.

Persons conducting independent assessments are technically qualified and knowledgeable.

Results of independent assessments are analyzed to establish corrective actions.

Corrective actions from assessments are tracked and monitored with results appropriately reported to management.

Contractor management system includes a "lessons-learned" reporting mechanism.

Lines of Inquiry:

- Do managers view their participation in the assessment process as essential?
- How are managers informed of quality assurance problems?

- Has the laboratory established a schedule for management assessments that will enable review of each operational area at least once every three years?
- How do organizations identify and define their significant processes and activities and ensure that these are being assessed on an at least three-year cycle?
- Does the contractor emphasize the importance of self-assessments and ensure their performance?
- Has the laboratory established and conveyed expectations to comply with contractual requirements to perform self-assessments?
- Are laboratory organizations self-assessment processes described in documented procedures?
- Do laboratory organizations establish qualification requirements for those assigned to perform self-assessments?
- Do methods for detecting, categorizing, and preventing quality problems provide for identifying the causes of problems, and include prevention of recurrence as a part of corrective action planning?
- Are corrective actions developed and implemented for problems, tracked to completion, and verified before closure?
- Has contractor management implemented a program of independent assessments?
- Are independent assessments team members technically qualified and knowledgeable?
- Are results of independent assessments analyzed to determine the appropriate corrective actions to be initiated?
- Is there a mechanism for the laboratory to assess the extent of condition and the applicability of corrective actions to other organizations?

Documentation and Records

Records management system meets the requirements of life-cycle records management.

Records management program complies with established requirements in all formats.

Scientific and technical information program meets the requirements of DOE O 241.1A.

Document control system is effective in supporting management policy, actions and communication to workers.

Schedules for records retention and disposition are consistent with contractual and regulatory requirements.

Lines of Inquiry:

- What policies and procedures address quality-related topics such as peer review, self-assessment, corrective actions, and quality improvement?
- Is there a process for determining what quality records must be generated?
- Has the contractor implemented a formal records management program that meets the requirements of life-cycle records management?

- Is records management training provided for all personnel with records management responsibilities?
- Does the laboratory have a vital records management program?
- Does the laboratory have a management system for hard-copy records, as well as electronic copies?
- Are records dispositioned, retained and stored in accordance with contractual and regulatory requirements?
- Are there processes that ensure that facility documents reflect actual facility configuration and design requirements?
- Have records requirements been defined (e.g. how records are identified, reviewed, approved, distributed and maintained) and responsible persons assigned?
- What is the organization's internal policy on control of policies, program documents, program implementation plans, and procedures?
- Does the laboratory have a scientific and technical information program that meets DOE and Fermilab requirements?

Personnel Training and Qualification

Work requirements for employees are defined and training provided.

Management plans for and commits resources to facilitate training and qualification of personnel.

Management solicits and encourages worker input to training content and execution.

Training program specifies the training records to be maintained.

Lines of Inquiry:

- Has the contractor established qualification requirements for workers?
- Is the training system documented (e.g., manual, procedures, lesson plans, etc.)?
- Has a training needs assessment program been implemented?
- Do training personnel, managers, and workers understand how qualification and training requirements are established, documented and implemented?
- How is job-specific training being implemented?
- How are qualification and training requirements modified based on changing conditions or new types of work?
- How does management ensure that users or those transferred into another position meet the appropriate qualification requirements?
- How does the laboratory maintain knowledge of the qualification and training status of employees?
- What specific training is provided for persons responsible for those processes that support quality, e.g., calibration, design control?
- How is the adequacy and effectiveness of the laboratory training organization assessed?

- Does management assess services provided by the training organization?
- Does management solicit input from workers regarding the adequacy of training?
- Are mechanisms in place to provide line management with feedback as a way to improve the training programs?
- How does management assure that training is current?
- Do training requirements specify periodic re-training/refresher-training?
- Are training requirements reflected in central database as directed by Fermilab policy?
- Does the laboratory personnel performance review process include and reinforce quality requirements?

Design and Procurement

Contractor's design process provides controls for design inputs, outputs, verification, changes and configuration control.

Design programmatic, technical, and administrative organizational interfaces are identified and controlled.

Methods for conducting a "tailored" approach to design are established.

Design products are verified and/or validated prior to their approval and implementation.

As-built conditions for structures, systems and components are provided in design documents.

Design inputs include contractual requirements and user expectations.

Design process includes use of approved computer codes for preparing designs and documentation.

Existing procurement management systems adequately respond to end-use requirements.

Procurement process provides for the identification of inspections and tests to ensure conformance with specifications.

Assessments of supplier capability and facilities include a review of the supplier history.

Qualified supplier performance is periodically monitored.

Lines of Inquiry:

- Has the contractor established design management processes?
- Does the contractor use a "tailored" approach in selecting the applicable design control requirements to be applied?

- Does quality program include requirements to develop design documents and document changes?
- Are contractual requirements and expectations for end-use reflected in documentation?
- Does the laboratory engineering standards manual address quality criteria?
- How are technical discrepancies in design and their resolutions documented?
- Are design outputs maintained current to reflect actual installed status or "as-built" configuration?
- Is there a specific quality review process for high risk items?
- Does the contractor organization have a process for verification of the adequacy of software used for design?
- Do the management controls for contractor procurement comply with applicable contractual and regulatory requirements?
- Does management assure sufficient definition of the requirements the procurement must satisfy?
- Are item/service requirements adequately conveyed to the supplier?
- How does the laboratory ensure that prospective suppliers are capable/qualified to supply the desired items/services?
- How are items/services checked to ensure they meet specified requirements?
- Do the procurement control processes ensure appropriate flow-down of applicable requirements of the laboratory contract to its contractors/suppliers?
- Do the procurement control processes provide for requiring contractors/suppliers flow-down requirements to sub-tier suppliers?
- Does the contractor review of suppliers include periodic follow-on reviews?
- What quality requirements apply when using the laboratory's ProCard?

Inspection/Acceptance Testing and S/C Item Control

Contractor has implemented a "tailored" approach for quality criteria, suspect/counterfeit (S/C) parts, and safety software.

Acceptance and performance criteria are established for inspecting and testing specified items, services, and processes.

Inspection/test results are evaluated and verified by qualified personnel.

Previously-accepted items are reviewed to determine if re-inspection and testing is necessary when requirement parameters change.

Measuring equipment and test equipment used for inspections, tests, monitoring, and data collection are calibrated, maintained, and controlled.

Management processes for the identification and control of S/C items are in place.

S/C part identification and control process is applied from manufacture through delivery, installation, or use.

Items and materials are maintained and stored to prevent their damage, loss, or deterioration.

Lines of Inquiry:

- Does each laboratory organization implement a system for determining which items/services must be inspected and/or tested to determine acceptability?
- Are test personnel performing validation inspections independent of verification activities?
- Does the contractor inspection/test acceptance program provide for identification and storage requirements of accepted items?
- Has the contractor specified qualifications for personnel who perform inspections and tests?
- Does the laboratory have a system in place to decide what monitoring and data collection equipment/instrumentation needs to be calibrated?
- Does the laboratory provide for the maintenance of calibrated equipment/ instrumentation, establish calibration accuracies/tolerances, and re-calibration frequencies?
- Does the laboratory provide for the evaluation of previously-generated measurements when equipment/instrumentation is found to be out of calibration?
- Does the laboratory management system address software quality assurance?
- Has the laboratory implemented software quality requirements for software associated with laboratory safety systems?
- Does the contractor have a program for identifying and controlling S/C items?
- Does the contractor have a program for monitoring and controlling items outside of typical procurement processes?
- How does the laboratory ensure that items and materials are maintained and stored to prevent their damage, loss or deterioration?

Quality Improvement

Line management and workers cooperate to identify quality processes to be improved.

Quality problems are identified, evaluated, causes and significance determined, and management action documented.

Contractor management emphasizes the importance of preventing quality problems.

Contractor management encourages employee participation in suggesting, exploring and implementing new ideas.

Quality problems from relevant internal and external information sources are reviewed and analyzed.

Effectiveness of quality assurance program improvements is monitored and tracked.

"Root causes" of quality problems are addressed in corrective action plans to prevent recurrence.

A "lessons learned" program has been implemented to identify potential quality improvements.

Lines of Inquiry:

- Are there documented processes for detecting and preventing quality problems?
- Are there thresholds for reporting quality problems?
- Are timely assessments scheduled on the basis of the importance of the activity, past performance, and potential weaknesses?
- Does contractor management encourage employee awareness and participation in suggesting, exploring and implementing new quality improvement ideas?
- Has the contractor established a program to analyze quality-related information from relevant internal and external sources?
- Are the methods for detecting and preventing quality problems documented in a procedure at the organization-level?
- Are organization personnel trained on methods for detecting and preventing quality problems?
- Does the contractor use a tracking system for effective follow-up on actions to improve quality?
- Has the contractor established a program where activities that do not meet established requirements are identified, isolated and controlled?
- Has the contractor implemented a "lessons learned" reporting mechanism for quality improvement?
- Does the laboratory have a system for sharing best practices across the laboratory and as appropriate across the DOE complex?
- Does the laboratory implement a lessons-learned program that analyzes problems, corrective actions, and best practices from other facilities/organizations?
- Does the laboratory have mechanisms to verify effectiveness of corrective actions?

Appendix E

Team Member Qualifications

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Team Member Qualification Summary

Name: DeVaughn R. Nelson
Employer/Normal Work Assignment: Department of Energy, Office of Science/Senior Health Physicist
Objective Assigned: Team Leader
Education:
- BA, St John's University
- MS, Vanderbilt University
- Ph.D., University of Tennessee

Experience:
- US Army Reactor Safety, 1959
- Physics Instructor, St John's University, 1959-60
- Physics Research, Oak Ridge National Laboratory, 1960-72
- USAEC, Directorate of Licensing, Environmental Project Manager, 1972-74
- USEPA, Federal Radiation Council (FRC), Presidential Guidance: Radiation Protection Guidance to Federal Agencies: Use of Diagnostic X Rays & Occupational Workers.
- USDOE, EH Coordinator, Advisory Panel on Accelerator Radiation Safety (APARS)
- USDOE, EH Manager, DOE 5480.11, Radiation Protection for Occupational Workers
- USDOE, SC Manager, DOE 5480.25 – DOE O 420.2B, Safety of Accelerator Facilities
- USDOE, SC Manager, SC Emergency Management Program
- USDOE, SC Manager, DOE Technical Standards Program
- USDOE, SC Manager, DSC SPAT 12 – Attributes of Effective Implementation
- USDOE, SC Member, Convened Group, Necessary and Sufficient Process, LBNL
- USDOE, Sub-Team Lead, Integrated Safety Management System Verification, PNNL
- USDOE, Team Lead, Integrated Safety Management System Verification, TJNAF
- USDOE, Team Lead, Integrated Safety Management System Verification, SLAC
- USDOE, Team Lead, Integrated Safety Management System Verification, RESL
- USDOE, SC Manager, SC COOP Program
- USDOE, SC Manager, DOE G 420.2-1, Accelerator Facility Safety Implementation Guide

Name: Judith Malsbury
Employer/Normal Work Assignment: Princeton Plasma Physics Laboratory, Head, Quality Assurance Division
Objective Assigned: Team Member – Review of Technical Division
Experience:
- BA, Douglass College, Rutgers University, Mathematics
- MS, Stevens Institute of Technology, Computer Science
- Experience in software design and development
- 24 years experience in Quality Assurance
- Division is responsible for Laboratory Quality Control, Procurement Quality Assurance, Audits, Tracking, Quality Plans and Procedures, quality support for projects
- American Society for Quality certifications
  Certified Quality Engineer, 1988
  Certified Quality Auditor, 1989
  Certified Quality Manager, 1995
  Certified Software Quality Engineer, 1998

Name: Tom McDermott

Employer/Normal Work Assignment: An Industrial Hygienist in the Office of Science Chicago Office (CH), Safety and Technical Services and also currently serves as the CH Issue Management Coordinator. Responsible for providing technical advice, support and assistance on occupational health and industrial hygiene issues, as well as providing ISM assessment and review services to various DOE Site Office and contractor management and staff. Advises senior management from DOE-CH and other Department elements on the technical merits of risk-based prioritization methodologies and application of risk management systems in an operating environment

Objective Assigned: Team Member – Review of Technical Division

Education and experience:

- BS in Comparative Physiology
- MS in Environmental Stressors, University of Wisconsin-Green Bay.
- He has over twenty years of occupational safety and health work experience.
- OSHA compliance officer
- Shift Supervisor for Atlantic Nuclear Services
- Original working group member chartered by Admiral Watkins with the development of a risk-based prioritization process for identifying, documenting, and allocating resources to ES&H needs and issues
- Served on ISM verification teams for INEEL, Ames Laboratory, Brookhaven National Laboratory (2004 and 2005), and Argonne National Laboratory
- Member of the PPPL ISM Re-verification, June 2006
- Team leader for the OCRWM Yucca Mountain ISM Phase I & II Verifications
- Mentored the Bechtel/SAIC (BSC), the Yucca Mountain contractor, to management team in their annual ISMS assessments in 2001 and 2002
- Active member of the Department's Response Team to DNFSB recommendation 98-1
- Member of the Department's Corrective Action Management Team (CAM). He has also led additional Focused ISM reviews at BNL in. Other recent accomplishments include:
- Led an assessment of the INEEL Industrial Hygiene Program as a result of local citizen groups and ID concerns with the Army's Abrams Armor production, 2002
- Member of CH led Review of the Brookhaven National Laboratory (BNL) Laser Safety Program as a result of the Sept 2003 BNL laser accident, as part of this review SC asked CH to analyze the past DOE and SC accidents for its Lessons Learned
- Lead an assessment of BNL's Industrial Hygiene Program, 2005
- Member of the DOE review board responsible for the February, 2005 DOE Special Operations Report-Laser Safety and Performance Expectations
- Member of the Type B Accident Investigation Board for the BNL April, 2006 Arc-blast Accident

Name: John W. Mashburn

Employer/Normal Work Assignment: UT-Battelle LLC, Oak Ridge National Laboratory, Spallation Neutron Source/Quality Assurance Representative

Objective Assigned: Team Member – Review of Accelerator Division and Particle Physics Division

Education and experience:

- BS, Engineering Physics, University of Tennessee, 1966
- MS, Physics, University of Tennessee, 1970
- Additional: all classes completed for Ph.D. in Physics, University of Tennessee, 1995
- Professional Engineering Registration, Tennessee #14855
- Certified as Quality Manager, Quality Engineer, Software Quality Engineer, and Quality Auditor by the American Society for Quality, 1990's
- Qualified as an ORNL Lead Auditor
- Co-led the quality assurance portion of ORNL re-engineering effort, 1997
- Developed and implemented a large part of the quality assurance program of an accelerator facility, the Spallation Neutron Source Project (SNS), 1998-2004
- Developed the ISO-9001 compliant Quality Manual for SNS operations phase QA, 2006
- 21 years engineering experience, including process engineering, nuclear engineering, and electrical engineering, in electronics manufacturing and nuclear plant design/construction environments
- 17 years quality assurance experience at DOE contractors (Y-12 Plant and ORNL)
- Experience includes Tennessee Valley Authority Nuclear Safety Review Staff, 1979-1986

Name: Kate E. Sordelet

Employer/Normal Work Assignment: Ames Laboratory, Quality Assurance officer

Review Objective: Team Member – Administrative Support

Education: BS in Business Administration - Transportation/Logistics, Iowa State University, 1985

Experience:

- Fourteen years quality assurance experience directing quality assurance initiatives, managing Environment, Safety and Health training, overseeing information management activities, conducting assessments, performing budget construction and formulating policies, procedures, plans and manuals
- Six years scientific and technical information experience including coordinating the patent approval process, performing information sensitivity reviews and serving as the Laboratory's Releasing Official for the DOE Office of Scientific and Technical Information
- Six years Energy Employee Occupational Illness Compensation Program Act experience including processing claims, answering claimant inquiries and coordinating public awareness meetings
- Seven years experience performing business systems reviews for an insurance corporation and several Boston area law firms
- Team Member, Integrated Safety Management System Verification, Yucca Mountain (2000)
- Chairperson /Facilitator for the Needs Assessment Team, Job Activity Specific Training Team, Calibration Committee, and the Continuous Quality Improvement Committee
- Lead auditor Certification (1992) and Radiological Worker II Certification for Radioactive Materials

Name: Dennis C. Parzyck
Employer/Normal Work Assignment: Department of Energy Fermi Site Office
Review Objective: Team Member - Fermilab Senior Management
Education:
Ph.D., M.S. Purdue University
B.A., St. Mary's University
Experience:

2001 - Pres.	Facility Representative, Department of Energy Fermi Site Office.
2000 - 2000.	Senior Advisor, ORNL Office of Independent Oversight
1998 - 2000.	Special Assistant to Director, Office of the ORNL Director.
1997 - 1998.	Director, ORNL Office of Environmental Protection.
1994 - 1997.	Special Assignment to Department of Energy Headquarters, ANL.
1990 - 1994.	Assistant Laboratory Director for ESH&Q Oversight, ANL.
1990 - 1990.	Director, ANL Office of Quality, Environment and Safety.
1988 - 1989.	Environmental Program Coordinator, ANL ESH Division.
1983 - 1988.	Director, ORNL Environment and Occupational Safety Division.
1978 - 1982.	Head, Health Studies, ORNL Health and Safety Research Division.
1977 - 1978.	Leader, Methodology Development, ORNL Health and Safety Research Division.
1976 - 1977.	Manager, Regional Studies, ORNL Environmental Sciences Division.
1974 - 1975.	Research Staff Member, ORNL Environmental Sciences Division.
1969 - 1970.	Nuclear Weapons Officer, U. S. Navy, Albuquerque, NM

Name: David Passarello
Employer/Normal Work Assignment: Brookhaven National Laboratory, Collider-Accelerator Department,
Objective Assigned: Team Member – Review of Accelerator Division and Particle Physics Division
Education and experience:
- BS, Scientific Engineering Technology, Fairleigh Dickinson University
- MS, Industrial Management, University of Stony Brook
- Assistant Director for QA for Relativistic Heavy Ion Collider Project, 1991-1999
- Group Manager for QA, Configuration Management, Documentation Contrl, and Security, 1999-present
- Extensive experience in quality assurance in a research environment and in commercial and military manufacturing: primary responsibility for development and implementation of QA programs that met ISO 9001, DOE O 414.1, and ASME NQA-1 quality management standards